DFW-APIC Government Affairs Committee
August 2021

APIC Public Policy and E-News Highlights (2021-2022)

http://cqrcengage.com/apic/home
https://apic.org/publications/enews/

6/25/21	FDA Updates Guidance on Flexible Bronchoscope Reprocessing The FDA issued a supplement to the 2015 safety communication on reprocessed flexible bronchoscopes, reminding healthcare facilities to follow manufacturer instructions for reprocessing and device maintenance, and providing a new recommendation for health care providers on single-use bronchoscopes. The goal of the recommendations is to reduce potential infection transmission between patients. This communication also includes updated information on medical device adverse event reports.
7/9/21	OSHA Extends Comment Period on COVID-19 ETS to August 20 OSHA has extended the deadline to submit comments on the COVID-19 emergency temporary standard (ETS) for an additional 30 days, to August 20. This does not change 14-day and 30-day implementation deadlines for compliance with the new rule. APIC is developing organizational comments, but if you or your facility would like to submit your own comments to OSHA, you may do so through APIC's "Take Action" portal.
7/9/21	FDA Advises Drug Manufacturers that Burkholderia cepacia Complex Poses Contamination Risk The FDA advises drug manufacturers of non-sterile, water-based drug products that *Burkholderia cepacia* complex (BCC or *B. cepacia*) continues to pose a risk of contamination. Read the FDA safety advisory.
7/13/21	Leapfrog Publishes Revised Fall 2021 Hospital Safety Grade In response to public comments on its Fall 2021 Hospital Safety Grade Methodology, Leapfrog has revised and republished the document. The revisions primarily address scoring of the hand hygiene measure, but do not address the number of observations. These revisions will be applied to the fall 2021 Hospital Safety Grade but will be re-evaluated prior to the spring 2022 Hospital Safety Grade. During this re-evaluation period, APIC will continue our dialogue with Leapfrog to encourage additional improvements for the Spring 2022 methodology. Read APIC's comments to Leapfrog on the Fall 2021 Hospital Safety Grade Methodology.
7/26/21	AHA Supports Mandatory COVID-19 Vaccination of HCP The American Hospital Association (AHA) issued a policy statement supporting mandatory COVID-19 vaccination of healthcare personnel (HCP). Noting that COVID-19 vaccinations are safe and effective, the AHA urges vaccination among all HCP, and urges hospitals and health systems to adopt mandatory COVID-19 vaccination policies for HCP. Read the AHA policy statement.
7/27/21	CDC Updates COVID-19 Guidance Due to Surge from Delta Variant The Centers for Disease Control and Prevention (CDC) is issuing a Health Alert Network (HAN) Health Advisory to notify public health practitioners and clinicians about the urgent need to increase COVID-19 vaccination coverage across the United States to prevent surges in new infections that could increase COVID-19 related morbidity and mortality, overwhelm healthcare capacity, and widen existing COVID-19-related health disparities. There is growing evidence that the Delta variant is at least twice as contagious as the original SARS-CoV-2 virus. Most cases of COVID-19 hospitalizations and death are in unvaccinated people; however, there are breakthrough infections in vaccinated people because of the surge of infections among the unvaccinated. This is a particular concern in nursing homes, where vaccinated residents are infected by unvaccinated staff.

7/29/21	FDA Extends Shelf Life of J&J COVID-19 Vaccine The FDA authorized an extension of the shelf life for the Johnson & Johnson's Janssen COVID-19 vaccine from 4.5 months to 6 months (an additional 45 days). The decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 6 months when refrigerated at temperatures of 36 – 46 degrees Fahrenheit (2 – 8 degrees Celsius). Vaccine providers should visit https://vaxcheck.jnj/ to confirm the latest expiration dates of vaccine, including those currently available for administration throughout the U.S. This extension applies to refrigerated vials of J&J/Janssen COVID-19 vaccine that have been held in accordance with the manufacturer's storage conditions.
7/30/21	FDA Revises EUA for REGEN-COV The FDA revised the Emergency Use Authorization (EUA) for REGEN-COV (casirivimab and imdevimab, administered together) to add an authorization of REGEN-COV for emergency use as post-exposure prophylaxis (prevention) for COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms) who are at high risk for progression to severe COVID-19, including hospitalization or death. REGEN-COV is not authorized for pre-exposure prophylaxis to prevent COVID-19 before being exposed to the SARS-CoV-2 virus -- only after exposure to the virus. REGEN-COV should only be used as post-exposure prophylaxis for specific patient populations. Prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19.
7/30/21	FDA Revises EUA for Olumiant The FDA revised the EUA for baricitinib (sold under the brand name Olumiant) now authorizing baricitinib alone for the treatment of COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Under the revised EUA, baricitinib is no longer required to be administered with remdesivir (Veklury). Baricitinib is not FDA-approved as a treatment for COVID-19.

Texas Register (2021-2022)

http://www.sos.state.tx.us/texreg/index.shtml **Key: X Pending**

Last Review Completed: 7/30/2021

Current Search Parameters for Review:

25 TAC: Chapters 2, 97, 133, 135, 200

30 TAC: Chapter 330; Subchapter Y

X	Date Filed	Action	Title/Ch./Rules/SB/HB	Topic / Comments
	3/1/21	***Referred to Public Health***	**HB 591**	Requires vaccination against bacterial meningitis for public school students
	6/15/21	***Signed by Governor – takes effect 9/1/21***	**HB 2211**	Pertaining to in-person hospital visitation during periods of disaster: The state government cannot issue a no visitor hospital order & all patients may have a visitor unless they fail screening or a physician documents they may not. Hospitals are allowed by law to require visitor PPE.

Prepared by 2021 APIC-DFW Governmental Affairs Committee:
Jasmine Cluck, Patti Grant, Stephanie Kreiling, Rachel Watson

AN ACT

relating to in-person visitation with hospital patients during certain periods of disaster.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 241, Health and Safety Code, is amended by adding Section 241.012 to read as follows:

Sec. 241.012. IN-PERSON HOSPITAL VISITATION DURING PERIOD OF DISASTER. (a) In this section:

(1) "Hospital" means a hospital licensed under this chapter.

(2) "Qualifying official disaster order" means an order, proclamation, or other instrument issued by the governor, another official of this state, or the governing body or an official of a political subdivision of this state declaring a disaster that has infectious disease as the basis for the declared disaster.

(3) "Qualifying period of disaster" means the period of time the area in which a hospital is located is declared to be a disaster area by a qualifying official disaster order.

(4) "Religious counselor" means an individual acting substantially in a pastoral or religious capacity to provide spiritual counsel to other individuals.

(b) A hospital may not during a qualifying period of disaster prohibit in-person visitation with a patient receiving care or treatment at the hospital unless federal law or a federal agency requires the hospital to prohibit in-person visitation during that period.

(c) Notwithstanding Subsection (b), a hospital may during a qualifying period of disaster:

(1) restrict the number of visitors a patient receiving care or treatment at the hospital may receive to not fewer than one;

(2) require a visitor to the hospital to:

(A) complete a health screening before entering the hospital; and

(B) wear personal protective equipment at all times while visiting a patient at the hospital; and

(3) deny entry to or remove from the hospital's premises a visitor who fails or refuses to:

(A) submit to or meet the requirements of a health screening administered by the hospital; or

(B) wear personal protective equipment that meets the hospital's infection control and safety requirements in the manner prescribed by the hospital.

(d) A health screening administered by a hospital under this section must be conducted in a manner that, at a minimum, complies with:

(1) hospital policy; and

(2) if applicable, guidance or directives issued by the commission, the Centers for Medicare and Medicaid Services, or another agency with regulatory authority over the hospital.

(e) Notwithstanding any other law, neither a hospital nor a physician providing health care services on the hospital's premises is subject to civil or criminal liability or an administrative penalty if a visitor contracts an infectious disease while on the hospital's premises during a qualifying period of disaster or, in connection with a visit to the hospital, spreads an infectious disease to any other individual, except where intentional misconduct or gross negligence by the hospital or the physician is shown. A physician who in good faith takes, or fails to take, an action under this section is not subject to civil or criminal liability or disciplinary action for the physician's action or failure to act under this section.

(f) This section may not be construed as requiring a hospital to:

(1) provide a specific type of personal protective equipment to a visitor to the hospital; or

(2) allow in-person visitation with a patient receiving care or treatment at the hospital if an attending physician determines that in-person visitation with that patient may lead to the transmission of an infectious agent that poses a serious community health risk.

(g) A determination made by an attending physician under Subsection (f)(2) is valid for not more than five days after the date the determination is made unless renewed by an attending physician.

(h) If a visitor to a hospital is denied in-person visitation with a patient receiving care or treatment at a hospital because of a determination made by an attending physician under Subsection (f)(2), the hospital shall:

(1) provide each day a written or oral update of the patient's condition to the visitor if the visitor:

(A) is authorized by the patient to receive relevant health information regarding the patient;

(B) has authority to receive the patient's health information under an advance directive or medical power of attorney; or

(C) is otherwise the patient's surrogate decision-maker regarding the patient's health care needs under hospital policy and other applicable law; and

(2) notify the person who receives the daily update required under Subdivision (1) of the estimated date and time at which the patient will be discharged from the hospital.

(i) Notwithstanding any other provision of this section, a hospital may not prohibit in-person visitation by a religious counselor with a patient who is receiving care or treatment at the hospital and who is seriously ill or dying for a reason other than the religious counselor's failure to comply with a requirement described by Subsection (c)(2).

(j) In the event of a conflict between this section and any provision of a qualifying official disaster order, this section prevails.

(k) This section does not create a cause of action against a hospital or physician.

SECTION 2. This Act takes effect September 1, 2021.

President of the Senate

Speaker of the House

I certify that H.B. No. 2211 was passed by the House on April 16, 2021, by the following vote: Yeas 140, Nays 5, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 2211 on May 28, 2021, by the following vote: Yeas 143, Nays 1, 1 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 2211 was passed by the Senate, with amendments, on May 25, 2021, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

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Governor